F. Certifications and Program Integrity (Subpart H)

Fraud and abuse can negatively affect both the quality of health care services rendered to Medicaid beneficiaries, and an MCO's, PIHP's, PAHP's, or PCCM's financial viability. Promoting program integrity within Medicaid managed care programs can protect against misspent Medicaid program funds, and promote quality health care services. Proposed subpart H of part 438 contains safeguards against fraud and abuse and requires that organizations with Medicaid contracts make a commitment to a formal and effective fraud and abuse program.

In proposed §438.600 we stated that the statutory basis for this subpart is under sections 1902(a)(4) and 1902(a)(19) of the Act. These sections require that methods be provided in the State plan for the proper and efficient operation of the plan and that safeguards are provided consistent with the best interests of the recipients.

In proposed §438.602 we provided that the certification and program integrity requirements contained in subpart H apply to MCOs and PIHPs as a condition for contracting and for receiving payment under the Medicaid managed care program.

In proposed §438.604 we provided that data, including enrollment and encounter data, must be certified and submitted to the State, if State payments are based on the data. We also specified that other information required by the State and information included in contracts, proposals, and other related documents must be certified. We also required in §438.604(b) that the MCO or PIHP certify that they are in substantial compliance with the terms of the contract.

In proposed §438.606 we required that certifications be provided concurrently with the data they relate to, and required that certifications be signed by the MCO's or PIHP's Chief Executive Officer, Chief Financial Officer, or an individual delegated authority to sign for one of these individuals. We proposed that the certifications must include attestations to the truthfulness, accuracy, and completeness of the data based on best knowledge, information, and belief.

In proposed §438.608 we required that each MCO or PIHP have administrative and management arrangements or procedures, including a mandatory compliance plan, designed to guard against fraud and abuse. This section also outlined the required elements to be included in the arrangements and procedures.

In this final rule we are making a technical correction to add two additional sources of authority. First, we are adding a citation to section 1903(m), which establishes conditions for payments to the State with respect to contracts with MCOs. Second, we are adding a new §438.610 to incorporate the requirements of section 1932(d)(1) of the Act. That provision of the statute is self-implementing, and therefore we did not include it in the proposed regulation. However, we are including the substance of the requirement in this final regulation to make it easier for the public to find all the relevant provisions in one place. Under the authority of section 1902(a)(4) of the Act, we are also applying these provisions to PIHPs and PAHPs.

We believe it is in the best interests of State Agencies, MCOs, PCCMs, PIHPs, PAHPs, and CMS to significantly aid in the fight against fraud and abuse and the requirements of this subpart work to achieve that goal.

Comment: One commenter proposed that we develop a standard form for certifications since we are requiring certifications by the Chief Executive Officer or the Chief Financial Officer or other person who is delegated the authority of the MCO or PIHP to certify data submitted.

Response: We disagree with the commenter as we wish to maintain State flexibility in this area. In §§438.604 and 438.606 respectively, we provide that data certifications are required if data are being used to set payments. We have described the source, content, and timing required for certifications. We do not, however, wish to be overly prescriptive and therefore, we are not prescribing the format of the certifications. If the commenter is requesting a sample format that could be used as a model certification form, one can be found on the CMS website at http://www.hcfa.gov/medicaid/letters/smd80700.htm in the document entitled, "Guidelines for Addressing Fraud and Abuse in Medicaid Managed Care" at appendix 2.

Comment: One commenter suggested that it is unclear as to when certifications are required and if the certifications of data to set payments is meant to reference payments under the current contract year or for proposed contract years. The commenter also believes that the requirements for certifications for substantial compliance with the terms of the contract are unclear.

Response: In §438.604(a) we require that MCOs and PIHPs provide certification of data requested by the State if payments to the MCOs and PIHPs are based on the data submitted, and in §438.606(c) we require that MCOs and PIHPs submit the certification concurrently with the data. This applies regardless of whether the data are used for setting

payments for current contract years, or for other contract years. If data are not being used to set payments, then certifications would not be required.

We agree with the commenter that clarification is necessary regarding certification for substantial compliance with the terms of the contract. We previously proposed, in §§438.604(b), that an MCO or PIHP must certify that it is in substantial compliance with the terms of its contract.

We understand the commenter's confusion regarding this requirement since the statute and regulations already require States to monitor compliance with contracts executed under this rule and provides sanctions to be used where certain requirements are not met. Further we would expect to require corrective action plans in situations in which a State is found to be out of compliance with these rules. Consequently, we believe that the requirements on States, MCOs, PIHPs, PAHPs, and PCCMs contained in §438.6 and elsewhere in this rule and the mechanisms for monitoring and enforcement are sufficiently clear that the requirements for "substantial compliance" in §§438.604 and 438.606 are unnecessary and we have deleted them from this subpart. Hence renumbering has taken place in these sections.

Comment: Several commenters believe that subcontractor certifications are necessary since MCOs could delegate functions to subcontractors including physicians, hospitals, and clinics as well as to administrative service organizations that collect data from network providers and report the data to the MCO and the State. The commenters argued that without accurate and complete data, States may not have the information necessary to set actuarially sound capitation rates. Commenters expressed opposing views

on this issue with one commenter believing that this requirement would be burdensome to plans and providers because of the complexities involved in obtaining provider certifications. Other commenters stated that subcontractor certifications are necessary to protect CMS and others against being defrauded or paying an MCO more than the amount to which it should be entitled. We received further suggestions that not having subcontractor requirements could undermine federal enforcement of the False Claims Act.

Response: We have considered the commenters' suggestions and we agree that subcontractors play an important role in an MCO's network. We require MCOs and PIHPs to certify all data they submit, which would include any data produced by subcontractors. We believe that MCOs and PIHPs should be held accountable for their subcontractors and their subcontractors' data. We believe that States must be able to rely on the MCOs' and PIHPs' certifications if they are to combat potential fraud and abuse, and continue to set capitation payments to MCOs and PIHPs appropriately. Therefore, we are only requiring in this subpart that data certifications be required of MCOs and PIHPs and not of their subcontractors. It is up to the State or the MCO or PIHP to determine whether subcontractor data is accurate. If data is not used to set payments, certifications by MCOs and PIHPs are not necessary.

Comment: We received opposing views about whether PAHPs should be exempt from the program integrity protections outlined in this subpart. One commenter suggested that PAHPs should be required to have fraud and abuse plans and data certifications to justify State payments, since fraud can be significant in ambulatory plans also. In contrast, another commenter believes we should require that fraud and abuse plans be implemented

only by entities with 10,000 enrollees or more.

Response: We clearly intend that PAHPs should work to combat against fraud and abuse. However, we are recognizing that it may not be appropriate to require those organizations to implement formal fraud and abuse plans, given that they generally have relatively few enrollees and provide a relatively narrow range of services. We believe that the benefits of requiring PAHPs to comply with the formal measures of subpart H in order to protect against fraud and abuse is outweighed by the level of burden placed on these organizations, which could place some plans at financial risk.

Consequently, we are only requiring that §§438.600 through 438.610 apply to MCOs, to PIHPs, and only to PAHPs and PCCMs where specifically noted. Typically, MCOs and PIHPs, which include at least some inpatient hospital or institutional care services, are larger, more complex organizations, and will in most cases, have higher enrollment levels.

We believe the more comprehensive plans (such as, MCOs and PIHPs) are likely to need to provide for more sophisticated methods for combating fraud and abuse and may also need to provide for compliance officers as part of their staff. This is because they are more complex organizations, and need to contract with a large number, and greater variety of providers. These plans typically serve more enrollees and provide more services. Furthermore, more complex organizations are likelier to include administrative staff that collect and report data, and that need more in-depth monitoring. We disagree with the commenter that the applicability of these requirements should depend on the PAHP's enrollment level, because enrollment can fluctuate, and we believe that approach would lead to arbitrary results.

Comment: A commenter suggested that we should not mandate the use of a compliance plan developed by a federal enforcement agency, that is, the OIG, that was intended for M+C plans.

Response: We agree with the commenter that to require the use of guidelines developed for a national program (such as, M+C) by a Federal enforcement agency would be overly prescriptive and could impede State flexibility in combating fraud and abuse. In §438.608 we require MCOs and PIHPs to have administrative and management procedures, including a mandatory compliance plan, designed to guard against fraud and abuse; however, we have not mandated the use of the compliance plan developed by the OIG. The commenter is correct that the compliance plan developed by the OIG is intended for M+C plans and not for Medicaid managed care plans. Further, we agree that it is important for States to have flexibility in combating fraud and abuse in the Medicaid program and we believe States can maintain that flexibility by developing their own compliance plans.